

Commercial/Healthcare Exchange Step Criteria Effective: August 11th, 2022

Step Therapy Name: Vivjoa

Step 1 Agent(s): Fluconazole 150 mg oral tablet

Step 2 Agent(s): Vivjoa (oteseconazole) oral capsule

Medication/Class Description:

Oteseconazole is an azole metalloenzyme inhibitor targeting the fungal sterol, 14 α demethylase (CYP51), an enzyme that catalyzes an early step in the biosynthetic pathway of ergosterol, a sterol required for fungal cell membrane formation and integrity. Inhibition of CYP51 results in the accumulation of 14-methylated sterols, some of which are toxic to fungi. Through the inclusion of a tetrazole metal-binding group, oteseconazole has a lower affinity for human CYP enzymes.

Required Medical Information:

1. Diagnosis
2. Previous therapies tried and failed

Age Restrictions: None

Prescriber Restrictions: None

Coverage Duration: 4 months

Exceptions for Stepped Medications

1. Recurrent Vulvovaginal Candidiasis. Approve if the patient meets the following criteria (A, B, and C):

Note: Recurrent vulvovaginal candidiasis is defined as three or more episodes of symptomatic vulvovaginal candidiasis within a one-year period.

A. Patient is NOT of reproductive potential; **AND**

Note: A patient who is NOT of reproductive potential is defined as: persons who are postmenopausal or have another reason for permanent infertility (e.g., tubal ligation, hysterectomy, salpingo-oophorectomy).

B. Patient is NOT lactating (i.e., breastfeeding); **AND**

C. Patient meets **one** of the following (i, ii, **OR** iii):

i. Patient has tried oral fluconazole as maintenance therapy AND had inadequate efficacy; **OR**

Note: Maintenance dosing for fluconazole (100 mg, 150 mg or 200 mg) is once weekly for 6 months.

ii. Patient meets one of the following (a, b, **or** c):

a. Oral fluconazole is not clinically appropriate for the patient due to drug-drug interactions, as determined by the prescriber; **OR**

b. Patient has a fluconazole allergy or intolerance, as determined by the prescriber; **OR**

c. Patient is being treated for a Candida species that is not susceptible to fluconazole, as determined by the prescriber; **OR**

iii. Patient has already started on Vivjoa therapy (to complete the course of treatment).

References:

1. Vivjoa™ capsules [prescribing information]. Durham NC: Mycovia; April 2022.
2. Vivjoa IBM Micromedex (database online) - Product Information: VIVJOA(TM) oral capsules, oteseconazole oral capsules. Mycovia Pharmaceuticals Inc (per manufacturer), Durham, NC, 2022. Available at: <https://www.micromedexsolutions.com>. Updated July 11, 2022. Accessed August 5, 2022

Policy Revision history

Rev #	Type of Change	Summary of Change	Sections Affected	Date
1	New Policy	New Policy	All	8/11/2022

